ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 14 07 66557 002

Manufacturer:

Comcotec Messtechnik GmbH
Gutenbergstrasse 3
85716 Unterschleißheim
GERMANY

Facility(ies):

Comcotec Messtechnik GmbH
Gutenbergstrasse 3, 85716 Unterschleißheim, GERMANY

Product Category(ies):

Software for control and documentation of disinfection and sterilization processes, for the release of sterilized medical devices, as well as for the calculation of stability data of sterilized medical devices

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

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Valid from: 2014-08-06
Valid until: 2019-08-05

588479

Date, 2014-08-07

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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